

ASSEMBLY BILL

No. 72

**Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members Bass, Evans, Gordon, Koretz,
Nava, Pavley, and Salinas)**

January 3, 2005

An act to add Division 114 (commencing with Section 130700) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as introduced, Frommer. Prescription drugs: manufacturer reporting requirement.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would require a prescription drug manufacturer that offers for sale, transfers, or otherwise furnishes prescription drugs to any person or entity in this state to submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer pertaining to those drugs. The bill would require the report to be consistent with federal laws applicable to information disseminated by drug manufacturers to a state governmental agency.

This bill would authorize the Attorney General to bring civil actions to enforce the reporting requirements and recover civil penalties that may be assessed by the Attorney General under the bill.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 114 (commencing with Section 130700) is added to the Health and Safety Code, to read:

DIVISION 114. PRESCRIPTION DRUGS

CHAPTER 1. DRUG MANUFACTURER HEALTH STUDIES
REPORTING

130700. (a) Any manufacturer of prescription drugs that offers for sale, transfers, or otherwise furnishes a prescription drug to any person or entity in this state shall submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer regarding each prescription drug it sells, transfers, or otherwise furnishes to a person or entity in this state.

(b) Subject to subdivision (c), the report shall include all studies pertaining to each prescription drug, whether the results are positive, negative, neutral, or inconclusive.

(c) The report shall be consistent with requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) that apply to the dissemination of information by a drug manufacturer to a state governmental agency.

130705. (a) The Attorney General may bring a civil action to enforce the requirements of Section 130700.

(b) (1) The Attorney General may assess and recover a civil penalty, as specified in paragraph (2), against a drug manufacturer for each finding of a violation of Section 130700 in a civil action brought under this section.

(2) A drug manufacturer that violates Section 130700 is liable for civil penalties of up to twenty-five thousand dollars (\$25,000) for each first violation, not less than fifty thousand dollars (\$50,000) nor more than one hundred thousand dollars (\$100,000) for each second violation, and not less than one hundred fifty thousand dollars (\$150,000) nor more than two hundred thousand dollars (\$200,000) for each subsequent violation.

(3) Any civil penalty recovered by the Attorney General under this subdivision shall be deposited in the State Treasury.

1 (c) In any action under this section in which judgment is
2 entered against the defendant, the Attorney General shall be
3 awarded reasonable attorney's fees together with the costs of
4 suit.

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